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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/517,597 03/02/00 WONG

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EXAMINER

FADMANABHAN, K

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/517,597

Applicant(s)

WONG ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, and subsequent cancellation of claims 11-34 in Paper No. 7 is acknowledged.
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is rejected as vague and indefinite for the recitation of “a solution form” in lines 6 and 12 because it is unclear what the intended meaning of this term is. Deletion of “form” following “solution” would overcome this rejection. The claim is also rejected as vague for the recitation of “capable of interacting” in line 7. It is unclear if the first peptide interacts with the second peptide or not. In addition, applicant should specify the nature of the recited interaction. Applicant should also replace “coil-form” in line 9 with “coil-forming”. Furthermore, applicant should replace “such” in lines 10 and 15 with “said”.

9. Claim 1 recites the limitation "the binding" in line 12. There is insufficient antecedent basis for this limitation in the claim. Applicant should also replace “is effective to measurably alter” with “measurably alters”, and delete the comma after “biosensor” in line 15.

10. Claim 4 recites the limitation "the presence". There is insufficient antecedent basis for this limitation in the claim.

11. Claim 5 recites the limitation "the presence". There is insufficient antecedent basis for this limitation in the claim. In addition, applicant should delete one of “the” or “said” after “wherein” in line 1 of the claim. Furthermore, applicant should replace “is effective to enzymatically release” with enzymatically releases”.

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12. Claim 6 recites the limitations "the binding" and "the presence" in lines 1 and 4, respectively. There is insufficient antecedent basis for these limitations in the claim. In addition, applicant should replace "such" with "said" and "is effective to measurably alter" with "measurably alters".

13. Claim 7 recites the limitations "the redox ion species", "the same charge", and "the binding". There is insufficient antecedent basis for these limitations in the claim. In addition, applicant should replace "is effective to enhance" with "enhances".

14. Claim 9 recites the limitations "the redox ion species" and "the binding". There is insufficient antecedent basis for these limitations in the claim. In addition, applicant should replace "is effective to reduce" with "reduces".

15. Claim 10 is rejected as vague and indefinite. It is unclear how claim 10 can recite the limitation of a positive first coil-forming peptide and properly depend on claim 8, which recites a negative first coil-forming peptide.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (WO 97/41424).

Lennox et al. teach a biosensor device and method, wherein the apparatus includes a biosensor surface and surface-bound two-subunit heterodimer complexes composed of first and second oppositely charged peptides that together form an alpha-helical coiled-coil heterodimer. The first peptide is attached to the biosensor surface, and the second peptide carries the ligand, accessible for binding by a ligand-binding agent. Binding is detected by a suitable detector. The biosensor surface can be prepared by the addition, to a template containing the first charged peptide, of a selected ligand attached to the second charged peptide. In a preferred embodiment, the biosensor surface includes a monolayer of hydrocarbon chains anchored at their proximal ends to the biosensor surface, and having free distal ends defining an exposed monolayer surface. The heterodimer complexes are preferably embedded within the monolayer, which is closely packed and ordered to form an effective barrier to current across the monolayer mediated by a

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redox ion species in an aqueous solution in contact with the monolayer. Binding of a ligand-binding agent to the ligand on the monolayer surface will increase current across the monolayer. The analyte of interest, which may be an anti-ligand binding agent, or a ligand or ligand analog that will compete with surface bound ligand for binding to a ligand-binding agent, will be introduced into a chamber of the biosensor. The chamber is filled with a solution containing an analyte and ionic species capable of undergoing a redox reaction at a charged electrode. Exemplary redox species are $\text{Fe}(\text{CN})_6^{3-}$ as a negatively charged species and $\text{Ru}(\text{NH}_3)_6^{3+}$ as a positively charged species. The analyte may be in free form or part of a complex. When the analyte is a ligand or ligand analog, there will be a ligand binding agent that may be immobilized on the chamber walls or present in unbound form within the chamber. A detector will determine the level of binding of ligand binding agent to the surface ligands. The pairing of the two oppositely charged peptides to form charge-neutral heterodimers in the monolayer results in a reduction in monolayer conductance. The reference does not specifically teach the effect of the redox ion species on current, nor does it teach the competitive nature of the assay.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Lennox et al. to obtain the claimed invention. Although Lennox et al. does not teach the reaction of a sample with a reaction reagent to obtain a first coil-forming peptide, this step must inherently occur, as a first coil forming peptide was obtained and used in the method of the reference. In addition, the recitation of relating the amount of unbound conjugate to the amount of analyte present in the sample is rendered obvious by the method of Lennox et al., as this recitation simply amounts to a competitive solid phase assay, which is well known in the art. As more analyte contacts its corresponding receptor, the conjugate is

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displaced (becomes unbound). Therefore, increasing analyte amounts results in decreasing conjugate amounts. It would have further been obvious at the time of the invention that a redox ion species that has the same charge as the second coil forming peptide would enhance ion-mediated current flow across the monolayer because the repulsion of like charges would disrupt the monolayer and allow flow through the barrier. Conversely, if the redox ion species has a charge opposite of the second coil forming peptide, there will be no repulsion and the monolayer will be stabilized, resulting in reduced current flow through the monolayer. Since $\text{Fe}(\text{CN})_6^{3-}$ has been disclosed as a suitable negatively charged species and $\text{Ru}(\text{NH}_3)_6^{3+}$ as a suitable positively charged species, it would have been obvious to use these ion carriers in the modified method.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/518,178. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps recited in the current application are also broadly recited in the apparatus claims of the '178 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-10 are rejected.

References: Cornell et al., Yamauchi et al., Zarling et al., Willner et al., Pirrung et al., Allen, Cozzette et al., Garnier, Turner et al., Buechler et al., Pittner et al., Gerber et al., and Chao et al., are cited as art of particular interest for teaching various sensor devices and methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

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June 19, 2001


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/23/01